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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT PAPER NUMBER

1655

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/502,520

Applicant(s)

MOON ET AL.

Examiner

Christopher R. Tate

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/4/05 4/25/05 5/16/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-23 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising Moutan root bark extract as an active ingredient for treating athlete's foot or osmidrosis, does not reasonably provide enablement for a composition comprising Moutan root bark extract as an active ingredient for preventing athlete's foot or osmidrosis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicants have reasonably demonstrated/disclosed that the claimed Moutan root bark extract is useful as a therapeutic agent for treating athlete's foot as well as osmidrosis (i.e., foul smelling sweat due to bacterial contamination) and/or reducing the risk thereof. However, the claims also encompass using the claimed extract to prevent these conditions which is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "treating", especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies (other than certain vaccination regimes) -

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including preventing such disorders as athlete's foot and osmidrosis (which are common conditions that many humans suffer from, and which are clearly not recognized in the medical art as being totally preventable conditions).

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to use the instantly claimed composition in a manner which would provide for the prevention of athlete's foot or osmidrosis.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 8, and 12-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 8 are rendered vague and indefinite by the phrase "is applied in the form of sprays ..." (recited at the end of each claim) because claims 4 and 8 are composition claims, not method claims. Thus, it is unclear if this phrase is attempting to define an intended use of the composition or something else. In addition, it is unclear by the plural term "sprays" (as well as the plural delivery form terms recited in claim 8) as to how many sprays are being defined by these claims (e.g., is the composition divided up and put into two or more spray bottles?).

Claim 12 is rendered vague and indefinite by the phrase "wherein the anti-microbial composition has an anti-microbial for" (line 8). It is unclear what the phrase "has antimicrobial for" therein is defining - e.g., is this phrase attempting to define that the anti-microbial composition has an anti-microbial activity against the recited microorganisms, that an additional antimicrobial agent is added which provides such activity, or something else?

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Claims 13 and 15 are rendered vague and indefinite by the respective phrases "...the compounds in a ratio of 1:5 to 5:1" and "...said compounds in an amount of 0.001 to 20%" because it is unclear by these phrases as to which and how many compounds are defined within the recited ratio - e.g., is the recited ratio range attempting to define Moutan root bark extract vs. one of the compounds (recited in claim 12) or vs. a combination of said compounds (and, if so, how many compounds)? This unclarity also holds true for claim 15 with respect to the amount range thereof - e.g., is the recited percentage amount range defining one compound or a combination of compounds (and, if so, how many compounds)? In addition, in claim 15, it is unclear as to what the first three recited percentage amounts ranges are in relation to - e.g., by weight, by volume, or something else?

Claim 21 is rendered vague and indefinite by the phrase "wherein said filler is a liquefied propane gas" because liquefied propane gas would not seem suitable for use as a pharmaceutical filler. It is unclear how liquefied propane gas could appropriately be used as a pharmaceutical filler within the instantly claimed antimicrobial composition. Further, the art does not appear to recognize propane gas as a pharmaceutical filler, based upon a patent literature search conducted by the Examiner. In addition, the instant specification does not appear to make any mention of the filler being liquefied propane gas. The only mention of this phrase is within claim 21. Is this phrase some type of typographical error?

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

As a formal matter, in claim 19, it appears that the terms "dextrine" and "cyclodextrine" are misspelled. The correct spellings should be --dextrin-- and --cyclodextrin--, respectively.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6-11, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Uchida et al. (JP 58023612 - DWPI, JPAB, and CAPLUS English Abstracts thereof), or by Mori et al. (JP 10194916 - Full computer English translation thereof).

A composition comprising an extract of Moutan root bark extract as an active ingredient therein is claimed. Dependent claims include the extract being obtained using one of the recited solvents including water and/or ethyl alcohol (ethanol), the composition being a medicine; cleansing agent, or a cosmetic, and the composition being in the form of cream (among others).

Uchida et al. teach a skin cosmetic (as well as cleansing and medicinal) composition (e.g., for treating acne), in the form of a cream, comprising an aqueous (water) or aqueous ethanolic extract obtained from the root bark of *Paeonia suffructicosa* (also termed Moutan root bark) as the active ingredient therein (see DWPI, JPAB, and CAPLUS English Abstracts). Although claimed as an intended use recitation, please note that the topical application of the reference composition to the skin acne would inherently act as an anti-microbial toward the acne-causing bacteria therein). Please also note that the composition taught by Uckida et al. would inherently provide the instantly claimed functional activities (e.g., provide antimicrobial activity against the various recited microorganisms).

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Mori et al. teach a skin cosmetic composition (as well as cleansing and medicinal) composition (e.g., antimicrobial composition), in one of various forms including a cream (as well as other topical forms), comprising a water, ethanol, or aqueous-ethanolic extract obtained from the root bark (cortex) of *Paeonia suffruticosa* (also termed Moutan bark) as an active ingredient therein (see entire English translation including Abstract and paragraphs [0012], [0014], [0015], [0018], [0021], [0022], Examples).

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Picard-Lesboueyries et al. (US 2002/0058010) and Uchida et al. (JP 58023612 - DWPI, JPAB, and CAPLUS English Abstracts thereof), in view of Sanchez et al. (US 5,296,472).

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Picard-Lesboueyries et al. beneficially teach an anti-acne cosmetic (as well as cleansing and medicinal) composition which comprises, or may comprise, antimicrobial compounds (such as triclosan, nystatin, tolnaftate), an extract of *Paeonia suffructicosa* root (Moutan root) - obtained from a commercial supplier, and other conventional cosmetic ingredients (such as fillers, fragrances, moisturizers, and propylene glycol) therein (see, e.g., Abstract, paragraphs [0007], [0072]-[0073], [0078], [0107], 0109], and claims). Please note that an extract of *Paeonia suffructicosa* root would appear to intrinsically comprise the root bark (cortex) since the root bark is a natural part of the root and Picard-Lesboueyries et al. do not teach that the root bark was removed therefrom. Picard-Lesboueyries et al. do not expressly teach how the *Paeonia suffructicosa* root was extracted, or the inclusion of certain other ingredients therein.

Uchida et al. beneficially teach a skin cosmetic (as well as cleansing and medicinal) composition (e.g., for treating acne), in the form of a cream, which comprises an aqueous (water) or aqueous-ethanolic extract obtained from the root bark of *Paeonia suffructicosa* (also termed Moutan root bark) as the active ingredient therein (see DWPI, JPAB, and CAPLUS English Abstracts). Uchida et al. also disclose that their composition comprises propylene glycol (a "skin moisturizer"), lanolin (a "skin permeation enhancer"), perfume (a "fragrance") - all within the instantly claimed amount ranges. Neither of the cited primary references expressly teaches the inclusion of dextrin or cyclodextrin therein.

Sanchez et al. beneficially teach that cyclodextrin-containing compositions can be topically used to effectively treat acne (since cyclodextrins are rather resistant to common amylolytic enzymes present in microorganisms of the human skin). Sanchez et al. also

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beneficially disclose that it is well known in the art to use cyclodextrins to encapsulate fragrances (see entire document including col 1, lines 55-56, and col 7, lines 3-8).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare an anti-acne composition comprising an extract (including an aqueous or aqueous-ethanolic extract) obtained from the root bark of *Paeonia suffruticosa* as an active ingredient therein in combination with another art-recognized antimicrobial compound (such as one of those disclosed by Picard-Lesboueyries et al) based upon the beneficial teachings provided by the two cited primary references with respect to the anti-acne activity such compositions afford, as discussed above. It would also have been obvious to one of ordinary skill in the art at the time the claimed invention was made to include cyclodextrin therein since Sanchez beneficially teaches that cyclodextrins are useful against acne and the acne-causing microorganisms, and also because Sanchez further discloses that cyclodextrins are conventionally used in the art to encapsulate fragrances - which both of the primary reference anti-acne compositions contain. The adjustment of this and other conventional working conditions (e.g., including other conventionally employed cosmetic ingredients therein including a particular conventional fragrance or filler, using a conventional topical form such as within a spray applicator, and/or determining appropriate result-effective amounts of such ingredients) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Please also note that such a composition would intrinsically provide the instantly claimed functional activities (e.g., provide antimicrobial activity against the various recited microorganisms).

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. (JP 10194916 - Full computer English translation thereof) and Nishibe et al. (JP 09158042 - Full computer English translation thereof), in view of Picard-Lesboueyries et al. (US 2002/0058010), and further in view of Sanchez et al. (US 5,296,472).

Mori et al. beneficially teach a skin cosmetic composition (as well as cleansing and medicinal) composition having excellent antimicrobial activity including against pimples (acne), whereby the composition is in one of various forms including a cream (as well as other topical forms), comprising a water, ethanol, or aqueous-ethanolic extract obtained from the root bark (cortex) of *Paeonia suffruticosa* (also termed Moutan bark) as an active ingredient therein. Mori et al. also beneficially disclose that the composition may include other conventional cosmetic ingredients therein including a polyhydric alcohol, propylene glycol, ethylene glycol, glycol ethers, polyethylene glycol esters, sorbitol, lanolin, moisturizers, and perfume (fragrance) as well as other fragrant herbal oils such as orange oil or avocado oil (see entire English translation including Abstract and paragraphs [0012]-[0019], [0021], [0022], Examples).

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Nishibe et al. also beneficially teach a skin cosmetic composition (as well as cleansing and medicinal) composition (for internal or external use - including in the form of a liquid or gel) having effective antimicrobial activity (including against bacteria and mold that breed on the body) comprising an extract obtained from the root bark (cortex) of *Paeonia suffructicosa* (also termed Moutan bark), whereby the extract solvent may be water and/or ethanol. Nishibe et al. also beneficially disclose that the composition may include other conventional cosmetic ingredients therein including propylene glycol, ethylene glycol, polypropylene glycol, [0028] glycol ethers, polyhydric alcohol derivatives such as polyhydric alcohol ethylene oxide, and natural perfume fragrances such as lavender, rosemary, spearmint, rose, and/or other herbal oils (see entire English translation including Abstract, and paragraphs [0004], [0007], [0008], [0016], [0028], [0031], [0040], [0067], and Examples/Tests). Mori et al. and Nishibe et al. do not expressly teach the inclusion of certain other claimed ingredients therein.

Picard-Lesboueyries et al. beneficially teach a skin cosmetic (as well as cleansing and medicinal) composition having anti-acne activity including having antimicrobial activity against *Proprioibacterium acnes* - an acne causative microorganism) which comprises, or may comprise, antimicrobial compounds (such as triclosan, nystatin, tolnaftate), an extract of *Paeonia suffructicosa* root (Moutan root) - obtained from a commercial supplier, and other conventional cosmetic ingredients (such as fillers, fragrances, moisturizers, and propylene glycol) therein (see, e.g., Abstract, paragraphs [0007], [0072]-[0073], [0078], [0107], 0109], and claims). Again, please note that an extract of *Paeonia suffructicosa* root would appear to intrinsically comprise the root bark (cortex) since the root bark is a natural part of the root and Picard-Lesboueyries et

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al. do not teach that the root bark was removed therefrom. Neither of the first three references expressly teaches the inclusion of dextrin or cyclodextrin therein.

Sanchez et al. beneficially teach that cyclodextrin-containing compositions can be topically used to effectively treat acne (since cyclodextrins are rather resistant to common amylolytic enzymes present in microorganisms of the human skin). Sanchez et al. also beneficially disclose that it is well known in the art to use cyclodextrins to encapsulate fragrances (see entire document including col 1, lines 55-56, and col 7, lines 3-8).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare an anti-microbial composition (including an anti-microbial composition useful against acne-causing microorganisms) comprising an extract (including an aqueous or aqueous-ethanolic extract) obtained from the root bark of *Paeonia suffruticosa* (i.e., Moutan root) as an active ingredient therein based upon the beneficial teachings provided by the two cited primary references with respect to the anti-microbial activity (including against acne-causing microorganisms) such a Moutan root extract-containing composition affords, as discussed above. It would also have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine such an antimicrobial Moutan root extract composition with an art-recognized antimicrobial compound (such as those disclosed by Picard-Lesboueyries et al) based upon the beneficial teachings provided by Picard-Lesboueyries et al., as discussed above. It would further have been obvious to one of ordinary skill in the art at the time the claimed invention was made to include cyclodextrin therein since Sanchez beneficially teaches that cyclodextrins are useful against acne-causing microorganisms, and also because Sanchez further discloses that cyclodextrins are conventionally used in the art to encapsulate

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fragrances - which all first three reference cosmetic compositions contain. The adjustment of this and other conventional working conditions (e.g., including other conventionally employed cosmetic ingredients therein including a particular filler, using a conventional topical form such as within a spray applicator, and/or determining appropriate result-effective amounts of such ingredients) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Please also note that such a composition would intrinsically provide the instantly claimed functional activities (e.g., provide antimicrobial activity against the various recited microorganisms).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moon et al. (US 6,241,975) in view of Kameyama et al. (JP 36036215 - JPAB English Abstract) and Nishibe et al. (JP 09158042 - - Full computer English translation thereof).

Moon et al. beneficially teach an oral cavity antimicrobial (antibacterial) composition for effectively treating periodontal disease and tooth decay (including against *Streptococcus mutans*) which comprises, or may comprise, a bioactive plant extract such as Moutan extract, triclosan, xylitol, and propolis therein. Moon et al. also disclose that the extraction may be carried out

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using an alcohol or via steam distillation (which reads upon water extraction) - see entire document including Abstract; col 2, lines 1-49; col 4, lines 31-42; col 5, lines 4-27; col 6, Table 2). Moon et al. do not expressly teach using a Moutan root bark extract, nor using water and/or ethanol for extraction thereof.

Nishibe et al. beneficially teach a composition (for internal or external use - including in the form of a liquid or gel) having effective antimicrobial activity and which is useful in the oral cavity. The reference composition comprises an extract obtained from the root bark (cortex) of *Paeonia suffruticosa* (also termed Moutan bark) as the active ingredient therein. Nishibe et al. also beneficially discloses that the extract solvent may be water and/or ethanol (see entire English translation including Abstract, and paragraphs [0007], [0008], [0031], [0040], [0067], and Examples/Tests).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to employ an aqueous or aqueous-ethanolic extract obtained from the root bark (cortex) of *Paeonia suffruticosa* (also termed Moutan bark) within the Moutan extract-containing oral cavity composition taught by Moon et al. based upon the beneficial teachings provided by Nishibe et al. with respect to the demonstrated antimicrobial activity such a Moutan bark affords. The adjustment of particular conventional working conditions (e.g., determining an appropriate combination and/or amount of such ingredients from among those taught by the cited references) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Please also note that such a composition would intrinsically provide the instantly claimed functional activities (e.g., provide antimicrobial activity against the various recited microorganisms).

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Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

With respect to the USC 102 and 103 rejections set forth above, it is noted that the cited references do not necessarily teach that the compositions disclosed or suggested therein can be used in some of the manners instantly claimed (e.g., for preventing osmidrosis, for sterilization and disinfection of animals and animal breeding farms, as an anti-foot-and-mouth disease composition, etc). However, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in those taught and/or reasonably suggested by the cited references. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art compositions. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Further, please note that when applicant claims a composition in terms of function and the composition of the prior art appears to be the same, the Examiner may make a rejection under both 35 U.S.C. 102 and under U.S.C. 103 (see, e.g., MPEP 2112).

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Christopher R. Tate
Primary Examiner
Art Unit 1655